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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,438	12/03/2001	Liming Yu	TNX95-02ABB	8540
26839	7590	10/28/2004	EXAMINER	
TANOX, INC. 10301 STELLA LINK HOUSTON, TX 77025			UNGAR, SUSAN NMN	
			ART UNIT	PAPER NUMBER
			1642	

DATE MAILED: 10/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/005,438

Applicant(s)

YU ET AL.

Examiner

Susan Ungar

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on August 27, 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 14-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) 14-22 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152). |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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1. Claims 14-22 are pending in the application and are currently under prosecution.
2. In view of Applicant's preliminary amendment, the previous restriction requirement is hereby withdrawn.
3. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
4. It is noted that the claims of the instant application have been determined to include linking claims. Claims 14 links Groups 1-4. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 14. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group 1. Claims 14-16, 18-19 are drawn to an IFN-Fc hybrid molecule comprising an interferon alpha2a molecule joined at one end to a chain of an Fc fragment without any linker between the two molecules, or a function variant thereof,, classified in Class 540, subclasses 350, 389.1.

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Group 2. Claims 14-16, 18-19 are drawn to an IFN-Fc hybrid molecule comprising an interferon alpha2ba molecule joined at one end to a chain of an Fc fragment without any linker between the two molecules, or a function variant thereof, classified in Class 540, subclasses 350, 389.1.

Group 3. Claims 14-19 are drawn to an IFN-Fc hybrid molecule comprising an interferon alpha2a molecule joined at one end to a chain of an Fc fragment without any linker between the two molecules further comprising a second interferon molecule joined at its end to the end of the other immunoglobulin Fc fragment chain, or a function variant thereof, classified in Class 540, subclasses 350, 389.1.

Group 4. Claims 14-19 are drawn to an IFN-Fc hybrid molecule comprising an interferon alpha2b molecule joined at one end to a chain of an Fc fragment without any linker between the two molecules further comprising a second interferon molecule joined at its end to the end of the other immunoglobulin Fc fragment chain, or a function variant thereof, classified in Class 540, subclasses 350, 389.1.

5. It is noted that the claims of the instant application have been determined to include linking claims. Claims 20 links Groups 5-8. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 14. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the

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claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group 5. Claims 20-22 are drawn to a method of treating a tumor comprising administering to a patient, in need of such a treatment, an IFN-Fc hybrid molecule comprising an interferon alpha2a molecule joined at one end to a chain of an Fc fragment without any linker between the two molecules, or a function variant thereof, classified in Class 540, subclasses 350, 389.1.

Group 6. Claims 20-22 are drawn to a method of treating a tumor comprising administering to a patient, in need of such a treatment, an IFN-Fc hybrid molecule comprising an interferon alpha2ba molecule joined at one end to a chain of an Fc fragment without any linker between the two molecules, or a function variant thereof, classified in Class 540, subclasses 350, 389.1.

Group 7. Claims 20-22 are drawn to a method of treating a tumor comprising administering to a patient, in need of such a treatment, an IFN-Fc hybrid molecule comprising an interferon alpha2a molecule joined at one end to a chain of an Fc fragment without any linker between the two molecules, or a function variant thereof, further comprising a second interferon molecule joined at its end to the end of the other immunoglobulin Fc fragment chain, classified in Class 540, subclasses 350, 389.1.

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Group 8. Claims 20-22 are drawn to a method of treating a tumor comprising administering to a patient, in need of such a treatment, an IFN-Fc hybrid molecule comprising an interferon alpha2b molecule joined at one end to a chain of an Fc fragment without any linker between the two molecules, or a function variant thereof, further comprising a second interferon molecule joined at its end to the end of the other immunoglobulin Fc fragment chain, classified in Class 540, subclasses 350, 389.1.

6. The inventions are distinct, each from the other because of the following reasons:

Inventions 1-4 as disclosed are biologically and chemically distinct, made by and used in different methods and are therefore distinct inventions.

Inventions 5-8 are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success.

The inventions of Groups 1 and 5 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (i) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § 806.05(h)]. In the instant case the IFN-Fc hybrid molecule as claimed can be used in a materially different process such as affinity chromatography.

The inventions of Groups 2 and 6 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (i) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a

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materially different process of using that product [see *MPEP* § 806.05(h)]. In the instant case the IFN-Fc hybrid molecule as claimed can be used in a materially different process such as affinity chromatography.

The inventions of Groups 3 and 7 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (i) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § 806.05(h)]. In the instant case the IFN-Fc hybrid molecule as claimed can be used in a materially different process such as affinity chromatography.

The inventions of Groups 4 and 8 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (i) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § 806.05(h)]. In the instant case the IFN-Fc hybrid molecule as claimed can be used in a materially different process such as affinity chromatography.

The inventions of Groups 1 and 5-8 are not at all related because the IFN-Fc hybrid molecule of Group 1 is not used in any of the methods of Groups 5-8.

The inventions of Groups 2 and 4, 6-8 are not at all related because the IFN-Fc hybrid molecule of Group 2 is not used in any of the methods of Groups 4, 6-8.

The inventions of Groups 3 and 4-5, 8 are not at all related because the IFN-Fc hybrid molecule of Group 3 is not used in any of the methods of Groups 4-5, 8.

The inventions of Groups 4 and 5-7 are not at all related because the IFN-Fc hybrid molecule of Group 4 is not used in any of the methods of Groups 5-7.

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7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

10. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

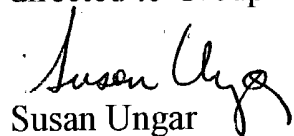
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (571) 272-0837. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 308-0787. The fax phone number for this Art Unit is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.



Susan Ungar
Primary Patent Examiner
October 25, 2004